

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Gentz et al.

Docket No.: PF454P1

Patent No.: 7,186,800

Confirmation No.: 7173

Issued: March 6, 2007

For: Tumor Necrosis Factor Receptors 6 Alpha & 6
Beta

**RESPONSE TO THE DECISION ON REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT**

MS Office of Patent Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

On August 27, 2010, the Commissioner for Patents denied Patentees Request for Reconsideration of Patent Term Adjustment. Because this decision was based upon an incorrect reading of applicable statutes and ignores guidance issued by the United States Patent and Trademark Office, Patentees respectfully request that the Commissioner withdraw its previous decision and provide a Patent Term Adjustment of 1,686 days.

Calculation of Patent Term Adjustment

1. As discussed further below, Patentees are entitled to a PTA of 1,146 days for the delay under 37 C.F.R. § 1.703(a)(3) for the period beginning on the day after the date that is four months after a reply in compliance with § 1.113(c) was filed on November 20, 2001 and ending on May 9, 2005, which is the date of mailing of either an action under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151.

2. Patentees agree with the Office that they are entitled to a PTA of 23 days due to the Patent Office's delay from the day after the date four months after the issue fee was paid and all outstanding requirements were satisfied to the date issuance. *See* 37 C.F.R. §§ 1.702(a)(4) & 1.703(a)(6).

3. Patentees agree with the Office that they are entitled to a PTA of 1,464 days due to the Patent Office's delay from the day after the date three years after the application was filed to the date that the patent was issued, to the extent that such delay does not overlap with other periods of delay. *See* 35 U.S.C. §§ 154(b)(1)(B) and 154(b)(2) and 37 C.F.R. § 1.703(b).

However, Patentees disagree with the Office over the extent of overlap of this delay with other periods of delay. As explained further below, this delay overlaps with the 23 days of delay due to failure to issue the patent within four months of paying the issue fee in ¶ 2 and 798 days (out of 1,146 days) of the delay in ¶ 1 for failure to respond under 35 U.S.C. § 132 or 151 within 4 months of Patentee's reply. Thus, Patentees are entitled to a PTA of 643 days due to the 1,464 days of delay for not issuing the patent within three years of filing minus the 23 days of overlap with the delay in ¶ 2 and the 798 days of partial overlap with the delay in ¶ 1.

4. Patentees agree with the Office's calculation of 126 days of Applicant delay.

5. Thus, Patentees are entitled to $1,146 + 23 + 643 - 126 = 1,686$ days of PTA.

Failure to Respond under 35 U.S.C. § 132 or 151 within Four Months of Patentee's Reply

As noted above in ¶ 1, Patentees responded on November 20, 2001 to a Final Rejection by amending the claims and traversing the rejection. On January 17, 2002, the Examiner issued a communication to Patentees informing them that the amendments had been entered and all rejections previously presented had been withdrawn. A Notice of Allowance did not issue, however. Instead, the Examiner suspended prosecution pending resolution of a third party interference. Examination of the Application resumed on May 9, 2005, when the Examiner re-opened prosecution and entered new rejections under 35 U.S.C. §102 and §112.

Patentees previously sought in their December 3, 2007 Request for Reconsideration a Patent Term Adjustment to cover the 1,146 days between the filing of their November 20, 2001 response and the Office Action mailed on May 9, 2005 resuming prosecution. The Office denied this request, finding that the communication mailed January 17, 2002 constituted an Office Action within the meaning of 35 U.S.C. §154(b)(1)(A)(ii) and 37 C.F.R. §1.702(a)(2). Decision on Request for Reconsideration of Patent Term Adjustment, pages 4 & 5. The Office also found that no additional adjustment was due for the time period after the suspension was lifted because an action was taken within four months of the alleged lifting of the suspension. *Id.* Instead, the Office indicated that Patentees were only entitled to a total of 725 days of PTA for the three periods of suspension between January 16, 2002 to November 18, 2002, July 17, 2003 to February 8, 2004, and June 9, 2004 to January 8, 2005.

The Examiner's Communication of January 17, 2002 did not Satisfy the Requirements Imposed by 35 U.S.C. §154(b)(1)(A)(ii), 35 U.S.C. §132, 37 C.F.R. §1.702(a)(2), and 37 C.F.R. §1.703(a)(3)

For the reasons stated in Patentee's December 3, 2007 Request for Reconsideration, the Office's Decision on Request for Reconsideration of Patent Term limits the term of Patentees' patent rights by delays in prosecution that Patentees could not have prevented through diligent action. The arguments laid out in Patentee's December 3, 2007 Request for Reconsideration are incorporated by reference and only briefly summarized below.

Pursuant to 37 C.F.R. §1.703(a)(3), the period of adjustment under §1.702(a) includes:

The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with §1.113(c) was filed and **ending on the date of mailing of either an action under 35 U.S.C. 132**, or a notice of allowance under 35 U.S.C. 151, whichever occurs first. (emphasis added)

Pursuant to 37 C.F.R. §1.702(a)(2) and 37 C.F.R. §1.703(a)(3) **the Office** must issue a **response under 35 U.S.C. §132** not later than four months after the date on which a reply was filed. To qualify as an action under §132, an Examiner's Office Action must reject a claim, state an objection, or require further action by Patentees. 35 U.S.C. §132.

Contrary to the Office's assertion, the Examiner's communication of January 17, 2002 did not satisfy any requirement under 35 U.S.C. §132; the filing did not reject a claim, object to any portion of the application, or require further action by Patentees. Thus, the January 17, 2002 communication may not serve to limit the scope of Patent Term Adjustment due to Patentees. A response under 35 U.S.C. §132 was not mailed by the Office until May 9, 2005.

Based upon the foregoing, and pursuant to the express language of 35 U.S.C. §154(b)(1)(A)(ii), 35 U.S.C. §132, 37 C.F.R. §1.702(a)(2), and 37 C.F.R. §1.703(a)(3),

the Examiner's January 17, 2002 communication may not serve to limit Patentees' right to Patent Term Adjustment. Accordingly, Patentees' respectfully request reconsideration of the Office's previous decision denying Patentees a full Patent Term Adjustment.

Incorrect Determination of Overlap between Periods of Delay

As noted above in ¶ 3, the Office improperly determined that the 1,464 days of delay for not issuing the patent within three years overlapped with all of the delay between the November 20, 2001 response and the Office Action mailed on May 9, 2005 resuming prosecution. In particular, the Federal Circuit in *Wyeth v. Kappos* overruled the Office's interpretation of the term "overlap" under section 154(b). See *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Federal Circuit held that the Office's interpretation could not be reconciled with the plain language of the statute. *Id.* at 1372. For example, under the USPTO interpretation, an application is "*delayed* under [the B guarantee] during the period *before it has been delayed*." *Id.* at 1370 (emphasis in original). The *Wyeth* court rejected the USPTO interpretation and instead held that "the language of section 154(b) does not even permit B delay to start running until three years after the application is filed." *Id.* Accordingly, the Court held that if "an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(b)(2)." *Id.* at 1370.

The delay for not issuing the patent within three years did not begin until March 4, 2003, which is the day after the date three years after the application was filed. This delay overlaps with the 23 days of delay due to failure to issue the patent within four months of paying the issue fee in ¶ 2 and 798 days (out of 1,146 days) of the delay in ¶ 1 for failure to respond under 35 U.S.C. § 132 or 151 within 4 months of Patentee's reply.

Therefore, Patentees are entitled to a PTA of 643 days due to the 1,464 days of delay for not issuing the patent within three years of filing minus the 23 days of overlap with the delay in ¶ 2 and the 798 days of partial overlap with the delay in ¶ 1.

Patentees note that the Office also incorrectly calculated the overlap in periods of delay under the Office's incorrect interpretation that Patentees are only entitled to a total of 725 days of PTA for the three periods of suspension between January 16, 2002 to November 18, 2002, July 17, 2003 to February 8, 2004, and June 9, 2004 to January 8, 2005 (compared to the 1,146 days of PTA asserted by Patentees). In particular, the Office indicated that all of these 725 days of PTA overlapped with the delay for not issuing the patent within three years. However, the 306 days of PTA for the period of suspension between January 16, 2002 to November 18, 2002 do not overlap with the delay starting March 4, 2003 for not issuing the patent within three years. Thus, the 1,464 days of delay for not issuing the patent within three years overlaps with the 23 days of delay due to failure to issue the patent within four months of paying the issue fee in ¶ 2 and 419 days (out of 725 days) of the Office's interpretation of the delay due to the periods of suspension. Under this interpretation, Patentees are entitled to a PTA of 1022 days due to the 1,464 days of delay for not issuing the patent within three years of filing minus the 23 days of overlap with the delay in ¶ 2 and the 419 days of partial overlap with the delay due to the periods of suspension. Accordingly, should the Office uphold its previous decision following this Request for Reconsideration of PTA, **Patentees would still be entitled to $725 + 23 + 1022 - 126 = 1,644$ days of PTA.**

CONCLUSION

Based on the foregoing, Patentees respectfully request reconsideration of the Office's previous determination that Patentees are entitled to only 1,338 days of Patent Term Adjustment. Patentees submit that they are properly entitled to a full Patent Term Adjustment of 1,686 days.

In the event of a favorable decision based on this application, Applicants further request reimbursement of the fee which has been paid pursuant to 37 CFR § 1.18(e) for the present request, since payment of such fee was necessitated by a mistake of the Patent and Trademark Office. Please charge any fee due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

If any further information is required, please call the undersigned at the number listed below.

Dated: September 24, 2010

Respectfully submitted,

By /Vicki L. Healy/
Vicki L. Healy
Registration No.: 48,343
HUMAN GENOME SCIENCES, INC.
14200 Shady Grove Road
Rockville, Maryland 20850
(301) 315-2712